Hair Removal Using a Combination of Electrical and Optical Energies – Multiple Treatments Clinical Study Six Months Follow up

Antonio Del Giglio M.D., James Shaoul M.D.

Introduction

In the past decade, intense pulse light and laser has proven the ability to obtain long-term hair removal. Ease of operation and minimal adverse effects combined with the ability to treat large areas made hair removal the number one aesthetic procedure in aesthetic medicine.

Selective photothermolysis of hair follicles using light is based on the selective absorption of the hair shaft. Optical energy is delivered to the tissue and absorbed mostly by the hair shaft, while the epidermis and the surrounding tissue have minimal absorption. There are two kinds of light sources that provide energy at a high enough level to achieve thermal destruction of hair: lasers and intense incoherent light. Intense pulse light is a broadband white light source that usually is filtered in order to obtain the desired spectrum. Lasers are monochromatic and therefore working at a discreet wavelength that is typical to the specific laser in use. The differences between the results obtained with various wavelength ranges are not significant. In general, when a longer wavelength is used, treatment safety improves.

The primary challenge of photo-epilation is to deliver to the hair root the amount of energy required to destroy it, without damaging the epidermis (where the energy passes through). Unfortunately, the chromophore that gives the hair dark color - melanin, and absorbs the light, is the same pigment that is present in the epidermis. Both cooling and long pulse duration have an important role on decreasing the heating of the epidermis, with minimal reduction on treatment results, and allows the application of higher energy to the skin[4,5]. In some cases, this can be achieved using a long pulse Nd:YAG laser producing near-infrared light at 1064nm. This wavelength is not well absorbed by the melanin of the epidermis or the melanin in the shaft. To compensate for the lower absorption level and lower heat generation, higher energy fluence must be applied to the patient. However, this methodology is also limited: pulse duration cannot be increased infinitely, because if it exceeds thermal relaxation time, the heat will dissipate to the surrounding tissue and will not be localized around the hair follicle. Furthermore, if cooling is applied too intensively, it can cause skin damage.

Thus, optimization of light-based treatment has now reached the theoretical limit. In order to achieve a new level of safety and efficiency, innovation in the underlying technology is now required.

Study objectives

The multi-center clinical study was conducted in order to evaluate a new method of hair removal. The main idea behind the method is to decrease optical energy to the level that is safe for all skin types. The desired coagulation level of the hair follicle is reached by adding a different type of energy that is selectively absorbed by the hair structure. The use of conducted radio frequency (RF) as an additional energy source for the light energy should be voluble since the RF is not sensitive to melanin concentration in the shaft or epidermis.

Long term follow up on hair reduction by single and multiple treatments was performed at a six month interval. A variety of treatment sites, ages, hair color, and skin color was used in order to determine the clinical efficacy for long term hair removal

The study was conducted with the Syneron Medical Aurora DS hair removal system, which utilizes a combination of conducted electrical energy in the radio-frequency (RF) range and optical energy. Light pulse in the near infrared range was applied simultaneously with a pulse of RF energy. In the study, higher RF energy and lower optical energy was used for darker skin.

Methods and patients

60 male and female patients with Fitzpatrick's skin type 2 to 5 and various hair colors were selected for the study. Table 1, below, shows the distribution of patients by skin type. The age range of the patients was 18-46 years.

Table 1.

Skin Type	Number of patients
2	11
3	33
4	12
5	4

A variety of body sites were chosen for the study, as shown in Table 2., below. The face was the most prevalent site treated and studied.

Table 2.

Site	Number of patients
Facial	28
Bikini Line	2
Axilla	5
Legs	4
Trunk	21

In addition, 12 cases with white / blond hairs were treated to preliminary determine the ability of the Aurora DS to effectively treat light hairs.

Informed consent of all participants was obtained and the body sites to be treated were identified and photographed. A baseline hair count was obtained manually. The target areas were shaved prior to treatment. No topical anesthetic cream or other anesthetic was applied.

The Aurora DS system, which employs a combination of optical and conducted RF energy for hair removal, was used for the study. RF energy was applied to the skin surface via two electrodes embedded in the applicator of the handpiece. The shape and the distance between the electrodes are optimized for penetration of up to 4mm. It is important to note that RF energy absorbance does not depend on skin pigmentation, but is determined by the electrical parameters of the tissue. The frequency of the RF current in the pulse is optimized to penetrate through the skin surface and to be selectively absorbed by the hair follicle.

In the study, the optical energy range used varied from 15 to 30 J/cm^2, while the RF energy range was 10-20 J/cm^3. Skin temperature was maintained at approximately 5° Centigrade by the effective epidermal cooling provided within the applicator.

Treatment procedure and results

Patients received 2-3 treatment sessions, 3 months apart and the results were evaluated 3 months following the last treatment.

Treatment technique

In the study, transparent gel and water was used for skin hydration. Light pressure was applied via the applicator to the treatment sites in order to ensure good coupling of the electrodes to the skin surface. Treatment overlap of up to 20% was acceptable.

On patients and/or body sites with darker skin, lower optical energy was used, while higher optical energy was used on patients and/or body sites with lighter skin. Since RF energy is equally efficient for all hair colors, higher RF energy was used in cases where lower optical energy was used.

Immediate response

In contrast to other purely optical devices, the Aurora DS system uses a low level of optical energy, which leads to less heating of hair shafts. Hence, hair shaft evaporation was not commonly observed.

RF energy mainly affects the hair follicles, causing them to coagulate. Effective cooling protects the epidermis from the immediate perifollicular erythema and only perifollicular bleaching was observed after the pulse. Bleaching is a result of perifollicular coagulation, which causes the transparency of the perifollicular tissue to decrease. In most cases, perifollicular edema and erythema were delayed, appearing after 10 to 15 minutes. While transient erythema was observed in some patients, it disappeared within a few hours. As the cooling has the effect of delaying all side effects, the patients were asked to observe the treated site and to report any side effects noticed in the immediate hours or days following the treatment.

The photographs below depict an example of the effect on the hair follicle by treatment with light and conducted RF energies delivered by the Aurora DS hair removal system. No adverse effects to the surrounding skin were noted. Under normal, non-magnified conditions, there were no visible changes to the skin. Only under high magnification were changes observed.

As seen on the right hand side of Figure 1. The treated area was photographed through a zoom (x80) lens. The upper photograph shows the treated area before the pulse, while the lower photograph shows the same area immediately after the pulse. It is interesting to note the white rings (bleaching) that appear around the hair follicles. The picture was taken within a few minutes of the pulse being applied. The left side of Figure 1. shows the entire treated area through a standard camera lens before and after treatment.

Follow-up observation

During the first week after the treatment, no significant hair reduction was observed, which was the expected response, due to the time it takes for the hair to fall out of the follicle. Maximum reduction in hair was observed at 2 weeks to 2 months after a single treatment.

The study patients were retreated 3 months post the first treatment. Each patient received 2 treatment sessions according to the investigator's decision. All patients were observed 6 months after treatment. A clinical examination and hair count were employed to access the efficacy of the treatments. Clearance (see Table 3. below) was calculated as the ratio between the value of the baseline hair count taken immediately before the first treatment, and the value obtained at the 6-month post treatment hair count.

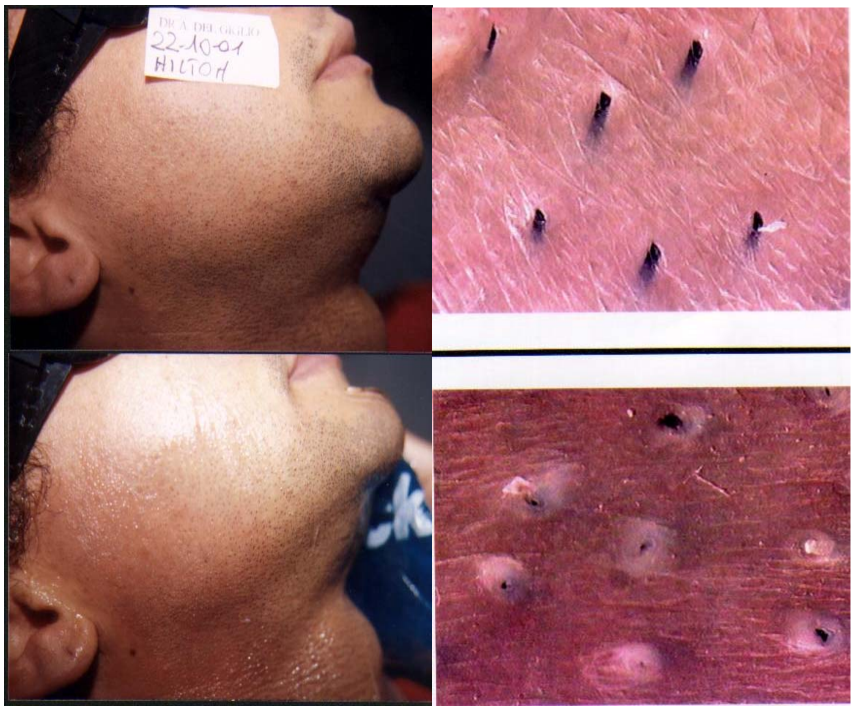

Figure 1. ***Treated site before and immediately after the treatment Left: total treated area. Right: treated area under zoom (x80).***

Table 3.

Site	**Average Clearance**
Axilla	84%
Bikini Line	76%
Legs	69%
Trunk	72%
Face	74%

Discussion

The clinical study results show that the best clearance was obtained at the Axilla site, with 84% reduction in hair. In most of the cases, the maximal RF energy (15-20 J/cm^3) was used. The level of optical energy varied, in the range of 15-28J/cm^2. Analysis of the study results shows that clearance after 6 months is almost entirely unrelated to the level of optical energy. In the optical energy range of 20-30 J/cm^2, results showed that clearance was determined by the level of RF energy, and that a higher RF energy level, in the range of 15-20 J/cm^3, should be used.

In order to understand the effect of the combination of conducted RF and light on the hair follicle at a depth of at least 2mm, a specific microscopic and histological study was performed at the Suntek2 institute in Verona, Italy. A 45-year-old male patient, with Fitzpatrick's skin type 3 and black hair, was accepted for treatment with the Aurora DS hair removal system under clinical study conditions.

Prior to treatment, a rectangular section of the patient's scalp, on the posterior aspect of his *Hippocratic Crown*, was shaved. Two pulses were applied to the shaved skin. After 30 minutes, 5cc of Lidocain 1% with Adrenalin was injected and a strip of skin with the follicles included was withdrawn with a multiblade scalpel. The scalpel was manipulated in a direction perpendicular to the follicle in order to provide a view of the follicle cross-section at the depth of 3.5mm.

Using this procedure, it was possible to recognize and photograph the immediate effect of the RF and optical energies on the hair follicle. The specimen was then sent to a laboratory, where the histological report and related pictures were produced.

The histology of the human skin was taken from the human scalp before and after treatment. Figure 2 shows histology taken at the edge of the treated area.

The right hand side of the photograph shows a normal follicle that was further from the center of the treated spot. There was no damage observed in this hair and follicle.

In the left follicle, a kind of melting of the follicle structure is clearly visible, particularly when it is compared with the right follicle, which was not damaged.

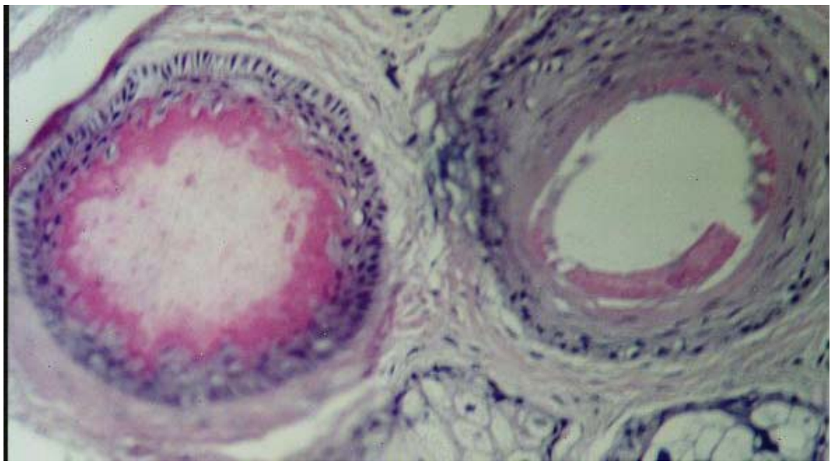

Figure 2. ***Skin with hair follicle histology at the depth of 3.5mm following treatment with Aurora DS.***

Light hair response

12 Patients with white, blond hairs participated in the study and were treated under the same protocol. Average clearance at 6 months is 52% based on treatment sites from facial, axilla and legs. Figure 3 shows a (x20) magnification of white hair before, and immediately after treatment.

Conclusion

Hair removal methodologies based purely on photo-epilation systems (whether laser-based or using intense flash lamps) have reached their full potential for efficacy and safety. Efforts to improve safety by using wavelengths that are not highly absorbed by melanin have not proven entirely successful, as the milder effect on the epidermis comes at the expense of efficacy in destroying the hair follicle.

The current study using a combination of conducted RF and optical energies for hair removal, as delivered by the Aurora DS hair removal system, showed that an energy pulse strong enough to cause the destruction of the hair follicle could be safely delivered without damaging the surrounding tissue. When pulses of RF energy in the higher range of 15-20 J/cm^3, combined with optical energy in the range of 15-25 J/cm^2 and

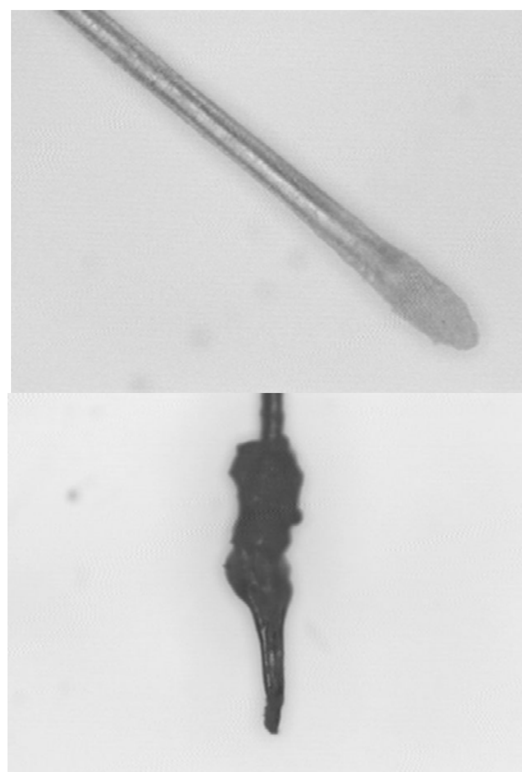

Figure 3: white hair before treatment, upper, and after, 28J/cm^2 of light and 20J/cm^3 of RF. lower

epidermal cooling, were applied to various body sites on the study subjects, no adverse effects were observed. Zoom photography and histological study immediately post-treatment showed that the required coagulation of the perifollicular tissue had been achieved, and clinical examination and hair count proved a high clearance rate (52-84%, depending on body site, and hair color) at 6 months post-treatment.

The treatments were well tolerated by the subjects, none of whom required topical or other anesthesia. The only post-treatment side effect observed was transient erythema, which disappeared within a few hours.

The efficacy, absence of adverse side effects, and ease of patient experience shown in the clinical study prove that the combination of conducted RF energy and optical energy, as delivered by the Aurora DS hair removal system, is an excellent methodology for hair removal in a broad cross section of the patient population.

References

1. M.C. Grossman C. Dierickx, W. Farinelli, T. Flotte, R. Anderson, Damage to hair follicle by normal mode ruby laser pulses. J Am Acad Dermatology 1996, 35: 889-894
2. M.H. Gold, M.W. Bell, T.D. Foster, S. Street, Long term epilation using the Epilight broad band, intense pulsed light hair removal system. Dermatology Surg 1997, 23:909-913
3. P.L. Bencini, A. Luci, M. Galimberti, G. Ferranti, Long-term Epilation with long-Pulsed Neodimium: YAG laser. Dermatology. Surg., 1999, 25:3: March:175-178.
4. V. Nururkar, The safety and efficacy of the long-pulse alexandrite laser for hair removal in various skin types. Lasers Surg Med, 1997, 10(suppl):189
5. B. Anvari, B.S. Tanenbaum, T.E. Milner, et al., Selective cooling of biological tissues: Application for thermally mediated therapeutic procedures. Physics in Medicine & Biology, 1995, 40:241-252.